

SynchroMed™ II Implantable Drug Infusion Pump was manufactured and sold by Defendants.

2. As a result of Mr. Radtkin's use of a SynchroMed™ II Implantable Drug Infusion Pump (herein "SynchroMed™ II"), he suffered injuries including, but not limited to, pump failure, medication withdrawal, debilitating back pain, and difficulty walking unassisted, mental health injuries, other personal injuries, medical expenses, and pain and suffering. In addition, Ms. Radtkin suffered injuries as a result of her husband's physical and emotional injuries. As a result of Mr. Radtkin's defective pain pump, Plaintiffs suffer the threat of future pain and other injuries.

THE PARTIES

3. Plaintiffs David Radtkin and Michelle Radtkin are citizens of Toledo, Ohio.

4. Mr. Radtkin Radtkin underwent SynchroMed™ II implantation to manage back pain at all times relevant herein.

5. Plaintiff Michelle Radtkin is the spouse of Mr. Radtkin Radtkin, who incurred damages, including emotional and other economic expenses, as a result of the injuries to her husband.

6. Defendant Medtronic, Inc. is a foreign corporation and citizen with headquarters located at 710 Medtronic Parkway, Minneapolis, MN.

7. Upon information and belief, Defendant Medtronic, Inc. manufactured SynchroMed™ II Implantable Drug Infusion Pump.

8. At all relevant times, Defendant Medtronic, Inc. has transacted and conducted business in the State of Ohio, and derived substantial revenue from interstate commerce.

9. Upon information and belief, Defendant Medtronic, Inc. packages, markets, and distributes SynchroMed™ II Implantable Drug Infusion Pumps.

10. At all relevant times, Defendant Medtronic, Inc. has engaged in the distribution, selling, marketing and/or introduction into interstate commerce, either directly or indirectly through third parties or related entities of SynchroMed™ II Implantable Drug Infusion Pump.

11. Defendant Medtronic Neuromodulation is a foreign corporation and citizen with headquarters located at 7000 Central Ave NE Minneapolis MN 55432.

12. Upon information and belief, Defendant Medtronic Neuromodulation manufactured SynchroMed™ II Implantable Drug Infusion Pump.

13. At all relevant times, Defendant Medtronic Neuromodulation has transacted and conducted business in the State of Ohio, and derived substantial revenue from interstate commerce.

14. Upon information and belief, Defendant Medtronic Neuromodulation packages, markets, and distributes SynchroMed™ II Implantable Drug Infusion Pumps.

15. At all relevant times, Defendant Medtronic Neuromodulation has engaged in the distribution, selling, marketing and/or introduction into interstate commerce, either directly or indirectly through third parties or related entities of SynchroMed™ II Implantable Drug Infusion Pump.

16. Defendant Medtronic, USA Inc. is a foreign corporation and citizen with headquarters located at 710 Medtronic Parkway, Minneapolis, MN.

17. Upon information and belief, Defendant Medtronic, USA Inc. manufactured SynchroMed™ II Implantable Drug Infusion Pump.

18. At all relevant times, Defendant Medtronic, USA Inc. has transacted and conducted business in the State of Ohio, and derived substantial revenue from interstate commerce.

19. Upon information and belief, Defendant Medtronic, USA Inc. packages, markets, and distributes SynchroMed™ II Implantable Drug Infusion Pumps.

20. At all relevant times, Defendant Medtronic, USA Inc. has engaged in the distribution, selling, marketing and/or introduction into interstate commerce, either directly or indirectly through third parties or related entities of SynchroMed™ II Implantable Drug Infusion Pump.

21. Defendant Medtronic Logistics, LLC is a foreign corporation and citizen with headquarters located at 7000 Central Ave NE Minneapolis, MN 55432.

22. Upon information and belief, Defendant Medtronic Logistics, LLC manufactured SynchroMed™ II Implantable Drug Infusion Pump.

23. At all relevant times, Defendant Medtronic Logistics, LLC has transacted and conducted business in the State of Ohio, and derived substantial revenue from interstate commerce.

24. Upon information and belief, Defendant Medtronic Logistics, LLC packages, markets, and distributes SynchroMed™ II Implantable Drug Infusion Pumps.

25. At all relevant times, Defendant Medtronic Logistics, LLC has engaged in the distribution, selling, marketing and/or introduction into interstate commerce, either directly or indirectly through third parties or related entities of SynchroMed™ II Implantable Drug Infusion Pump.

26. Defendant Medtronic Puerto Rico Operations Co. is a foreign corporation and citizen with headquarters located at Carretera 151, Bo. Villalba Arriba, Villalba, Puerto Rico.

27. Upon information and belief, Defendant Medtronic Puerto Rico Operations Co. manufactured SynchroMed™ II Implantable Drug Infusion Pump.

28. At all relevant times, Defendant Medtronic Puerto Rico Operations Co. has transacted and conducted business in the State of Ohio, and derived substantial revenue from interstate commerce.

29. Upon information and belief, Defendant Medtronic, Puerto Rico Operations Co. packages, markets, and distributes SynchroMed™ II Implantable Drug Infusion Pumps.

30. At all relevant times, Defendant Medtronic, Puerto Rico Operations Co. has engaged in the distribution, selling, marketing and/or introduction into interstate commerce, either directly or indirectly through third parties or related entities of SynchroMed™ II Implantable Drug Infusion Pump.

31. In the interest of clarity, this Complaint refers to Defendants Medtronic Inc., Medtronic USA, Inc., Medtronic Logistics, LLC, Medtronic Puerto Rico Operations Co., and Medtronic Neuromodulations as “Defendants.”

32. Defendants transacted business and maintained significant contacts in Ohio, where Plaintiffs were implanted with the SynchroMed™ II Implantable Drug Infusion Pump through the sales of SynchroMed™ II Implantable Drug Infusion Pump and other medical devices in Ohio.

33. At all times relevant, Defendants were engaged in the business of developing, manufacturing, distributing, selling, and/or introducing into interstate commerce, either

directly or indirectly through third parties, subsidiaries or related entities, the of SynchroMed™ II Implantable Drug Infusion Pump.

34. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assignees and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

35. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy, and joint venture.

JURISDICTION AND VENUE

36. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiffs and Defendants, and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

37. Venue is proper in the Northern District of Ohio, Western Division pursuant to 28 U.S.C.A. § 1391, as the sale and promotion of SynchroMed™ II, implantation and use of the SynchroMed™ II, and resulting injuries occurred within this district.

38. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitutions and pursuant to Ohio R. C. § 2307.382(1) and § 2307.382 (4) because Defendants transacted business in Ohio and caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this

district, and receive substantial compensation and profits from sales of SynchroMed™ II within this District.

39. Defendants expected or should have expected that their business activities could or would have consequences within the States of Ohio, as well as throughout the United States.

FACTS
SynchroMed™ II Implantable Drug Infusion Pump

40. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

41. The Medtronic SynchroMed™ II Implantable Drug Infusion Pump provides drug delivery for chronic therapy for severe spasticity, chronic intractable pain, and/or the management of severe chronic pain.

42. The device consists of an infusion pump connected to a thin, flexible catheter which delivers medication into the spinal canal.

43. The Medtronic SynchroMed™ II Implantable Drug Infusion Pump is manufactured by Defendants.

44. The federal Food and Drug Administration (FDA) approved Defendants' original Medtronic® Synchromed™ Pump and Infusion System on March 14, 1988.

45. The Medtronic SynchroMed™ II Implantable Drug Infusion Pump was approved on September 12, 2003.

46. The SynchroMed™ II is implanted under the skin and delivers the drug from the pump reservoir, through the pump tubing, check valve catheter port, and implanted catheter, to the infusion site.

47. The SynchroMed™ II is meant to deliver medication at a rate deemed therapeutically appropriate by the managing physician and is refilled by the managing physician when the low reservoir alarm of a pump sounds.

48. Defendants represented and marketed The SynchroMed™ II as a safe, proven, and effective way to manage chronic pain with fewer side effects and lower doses than systemic medication.

49. Defendants also represented and marketed the SynchroMed™ II as designed to help eliminate systemic opioids and provide effective pain relief.

50. Defendants also represented and marketed the SynchroMed™ II as intended to have a battery life of “4 to 7 years.”¹

51. The representations by Defendants were perpetuated directly and/or indirectly by Defendants, their sales representative, employees, distributors, agents and/or detail persons.

52. Defendants knew that Plaintiffs, their healthcare providers and the public had no way to determine the truth behind Defendants’ representations, as set forth herein.

FACTS REGARDING PLAINTIFFS DAVID AND MICHELLE RADTKIN

53. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

54. Mr. Radtkin Radtkin has postlaminectomy syndrome, multilevel degenerative disc disease, and hypertrophic changes with levoscoliosis and had been receiving pain medication via intrathecal pump for approximately 12 years prior to February 16, 2022.

¹ See <https://medtronic.com/us-en/healthcare-professionals/products/neurological/drug-infusion-systems/synchromed-ii.html>

55. Mr. Radtkin underwent his first SynchroMed™ II implantation in 2009, which was later revised in 2015.
56. On February 16, 2022, Mr. Radtkin's physician explanted the prior device and implanted the SynchroMed™ II at issue in this Complaint in accordance with Defendants' instructions. The insertion was without complication.
57. On February 17, 2022, Plaintiffs presented to the Toledo Hospital emergency room via emergency medical services for evaluation of Mr. Radtkin for nausea, vomiting, fever, urinary retention, opioid withdrawal delirium, and chest pain due to pain pump malfunction.
58. Upon diagnosing that Mr. Radtkin's symptoms were due to malfunction of the intrathecal infusion pump implanted the previous day, Mr. Radtkin was transferred and admitted to Mercy St. Vincent Hospital on February 17, 2022.
59. Upon arrival to Mercy St. Vincent Hospital, Mr. Radtkin diagnosed with and treated primarily for opioid withdrawal delirium (acute hyperactive) due to malfunction of the SynchroMed™ II pump.
60. During his course at Mercy St. Vincent Hospital, Mr. Radtkin was evaluated by providers who found "no definite significant kinking or pump catheter tubing issues."
61. On February 21, 2022, Plaintiff was discharged from Mercy St. Vincent Hospital.
62. On April 11, 2022, Mr. Radtkin underwent SynchroMed™ II pump removal due to "acute pump malfunction." with "no kinking found in site of intrathecal pain pump" findings upon removal.

63. Following the SynchroMed™ II malfunction and its removal, Mr. Radtkin suffered from debilitating withdrawal symptoms, leg weakness, impaired functional strength, impaired ability to ambulate, depression, irritability, anxiety, adjustment disorder.

64. As a result of Mr. Radtkin's injuries, Ms. Radtkin suffered the loss of companionship, society, services, and consortium of her husband.

CAUSES OF ACTION

COUNT I - DEFECTIVE MANUFACTURING/CONSTRUCTION

(Pursuant to O.R.C. §2307.74 et seq. and Common Law)

65. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

66. At all times relevant to this action, Defendants were the manufacturers and/or distributors, that produced, created, made, constructed, and/or assembled the SynchroMed™ II that was placed into the stream of commerce.

67. The SynchroMed™ II was expected to and did reach the ultimate users, including Plaintiffs, without substantial change in condition.

68. Mr. Radtkin had prior successful implantation and treatment with the same SynchroMed™ II model for approximately 7 years prior to his February 16, 2022 implantation.

69. Unlike the prior unit, Defendants' product at issue in this suit was defective in that, when it left the control of Defendant, the product did not conform in a material way to design specifications made by Defendant.

70. In their manufacture, sale, and distribution of SynchroMed™ II, Defendants:

- a. failed to manufacture the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;
- b. failed to conform with Defendants' own design specification so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs; and/or
- c. otherwise negligently or carelessly manufactured, distributed, or sold the product.

71. The SynchroMed™ II Implantable Drug Infusion Pump, which was manufactured, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants was defective in its:

- a. Manufacture and construction; and/or
- b. Failure to conform, when it left the control of Defendants, to their design specifications.

72. At all times herein mentioned, SynchroMed™ II was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said SynchroMed™ II was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.

73. By reason of the foregoing, the Defendant is liable to the Plaintiffs for the manufacturing of a product that is defective in that it did not conform at the time it left the control of Defendants, to design specifications made by Defendants.

74. While Plaintiffs believe and aver that Defendants acted negligently and recklessly, in the event Defendants is not found to have acted negligently or recklessly, Defendant is still liable for the damages and injuries suffered by Plaintiffs pursuant to Ohio Revised Code § 2307.01 et seq. and common law.

75. As a direct and proximate result of Defendants' violations of the Ohio Products Liability Act and the common law in their manufacturing a product that is defective,

Plaintiffs suffered physical pain and mental anguish, diminished enjoyment of life, medical, health, and incidental and related expenses.

76. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT II- DEFECTIVE DUE TO NONFORMITY WITH REPRESENTATION
(Pursuant to O.R.C. §2307.77 et seq. and Common Law)

122. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth fully at length herein.

123. Defendants represented and marketed The SynchroMed™ II as a safe, proven, and effective way to manage chronic pain with fewer side effects and lower doses than systemic medication.

124. Defendants also represented and marketed the SynchroMed™ II as designed to help eliminate systemic opioids and provide effective pain relief.

125. Defendants also represented and marketed the SynchroMed™ II as intended to have a battery life of "4 to 7 years."

126. Despite Defendants' representations of proven safety, effectiveness, fewer side effects, and alleged battery life of 4 to 7 years, Mr. Radtkin experienced acute pump malfunction within a day after SynchroMed™ II implantation.

127. In their manufacture, sale, and distribution of SynchroMed™ II, Defendants failed to conform with Defendants' own representations so as to avoid an unreasonable risk of harm to patients in whom the pump was implanted, including Mr. Radtkin.

128. The Defendants' product was defective in that, when it left the control of Defendant, the product did not conform to representations made by Defendant.

129. By reason of the foregoing, the Defendant is liable to the Plaintiffs for the manufacturing of a product that is defective in that it did not conform; at the time it left the control of Defendants, to design specifications made by Defendants.

130. While Plaintiffs believe and aver that Defendants acted negligently and recklessly, in the event Defendants is not found to have acted negligently or recklessly, Defendant is still liable for the damages and injuries suffered by Plaintiffs pursuant to Ohio Revised Code § 2307.01 et seq. and common law.

131. As a direct and proximate result of Defendants' violations of the Ohio Products Liability Act and the common law in their manufacturing a product that is defective, Plaintiffs suffered physical pain and mental anguish, diminished enjoyment of life, medical, health, and incidental and related expenses.

132. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT III - NEGLIGENCE

133. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth fully at length herein.

134. Defendants owed Plaintiffs and all consumers a duty of reasonable care in how it manufactured, sold, distributed, supplied, represented, and/or placed SynchroMed™ in the stream of commerce .

135. Defendants breached their duty of care and were negligent as described herein in the manufacture, selling, and distribution of SynchroMed™ II in one or more of the following respects:

- a. failing to manufacture the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;
- b. failing to conform with Defendants' own representations so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;
- c. falsely representing and promoting SynchroMed™ II was a safe and effective chronic pain management option;
- d. representing and marketing SynchroMed™ II as having a battery life of "4 to 7 years," when these representations by Defendants were in fact false.
- e. otherwise negligently or carelessly manufacturing, distributing, or selling the product.

136. As a direct and proximate result of Defendants' negligence, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

137. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT IV - BREACH OF EXPRESS WARRANTY

151. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

152. Defendants created express warranties in their selling, distribution, supply, promotion and marketing of SynchroMed™ II .

153. These include, but are not limited to, warranties that:

- a. SynchroMed™ II was a safe drug delivery option;
- b. SynchroMed™ II was a safe, proven and effective way to manage chronic pain with fewer side effects and lower doses than systemic medication;
- c. SynchroMed™ II as designed to help eliminate systemic opioids and provide effective pain relief; and
- d. SynchroMed™ II has a battery life of 4 to 7 years.

154. At the time of making such express warranties, Defendants knew or should have known that Defendants' SynchroMed™ II did not conform to these express representations and that SynchroMed™ II was not of merchantable quality, safe or fit for its intended use.

155. Plaintiffs relied on these warranties when choosing to have SynchroMed™ II implanted and would not have done so if they knew the representations were false.

156. Defendants breached each of these warranties to Plaintiffs in that Defendants' SynchroMed™ II was not of merchantable quality, safe and fit for its intended use.

157. As a direct and proximate result of Defendants' breached warranties, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

158. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT V- BREACH OF IMPLIED WARRANTY

159. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

160. By introducing SynchroMed™ II into the stream of commerce and promoting its use, Defendants impliedly warranted the product was merchantable, including: that SynchroMed™ II would be of average quality; that it would be fit for its ordinary purpose and use; and that it would conform to the promises made in its representations regarding the product.

161. Mr. Radtkin's SynchroMed™ II he received on February 16, 2022 was dangerous as alleged herein, was less effective than promised, was not of average quality, was not fit for its ordinary purpose and use, did not conform to the promises made in its representations regarding the product.

162. At the time they distributed SynchroMed™ II, Defendants knew or should have known that SynchroMed™ II was not merchantable.

163. Plaintiffs relied on Defendants' warranties when deciding to allow SynchroMed™ II units to be implanted in their bodies. They would not have allowed SynchroMed™ II to be implanted if they knew the product was not merchantable and was defective as described herein.

164. As a direct and proximate result of Defendants' breached warranties, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

165. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to

patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT VI- NEGLIGENCE INFLICTION OF EMOTIONAL DISTRESS

166. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

167. Defendants should have known and/or did know that their manufacturing defects could cause and would cause emotional distress to Plaintiffs and their families.

168. Defendants were negligent in causing Plaintiffs' emotional distress.

169. SynchroMed™ II caused Plaintiffs to suffer physical pain and mental anguish, diminished enjoyment of life, medical, health, and incidental and related expenses. These conditions directly and indirectly caused emotional distress in Plaintiffs.

170. As a direct and proximate result of Defendants' wrongful actions, Plaintiffs suffer from emotional distress.

171. Mr. Radtkin's emotional distress resulting from the malfunction of Defendants' device was extremely serious to the point of being debilitating and required professional mental health care.

172. Defendants' conduct was committed with, conscious disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT VII- LOSS OF CONSORTIUM
(AS TO PLAINTIFF MICHELLE RADTKIN)

174. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

175. As a result of the foregoing acts and omissions, and the resulting injuries, including, but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff David Radtkin, Plaintiff Michelle Radtkin has suffered the loss of companionship, society, services, and consortium of her husband.

COUNT VIII - PUNITIVE DAMAGES

176. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

177. Plaintiffs' injuries were the result of misconduct of Defendants that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question.

178. Defendants thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiffs and the public.

179. By the foregoing, the Defendants are liable to the Plaintiffs for punitive damages, for the manufacturing, producing, creating, making, constructing, and/or assembling a defective product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs each pray for judgment against the Defendants, jointly and severally, as follows:

- A. For an award of compensatory damages, including damages against Defendants and each of them for pain and suffering, medical and hospital expenses, loss of income, and other damages according to proof at trial in excess of \$75,000;
- B. For an award of punitive or exemplary damages against Defendants and each of them in excess of \$75,000;

- C. For reasonable attorneys' fees and costs;
- D. For pre-judgment interest; and
- E. For such further and other relief the court deems just, equitable, and proper.

Dated: February 14, 2024

Respectfully Submitted,

/s/Carasusana B. Wall

Carasusana B. Wall (0090234)

Ameena Alauddin (0102588)

Damon C. Williams (0101886)

ZOLL & KRANZ, LLC

6620 W. Central Ave., Suite 100

Toledo, OH 43617

Tel: (419) 841-9623

Fax: (419) 841-9719

cara@toledolaw.com

ameena@toledolaw.com

Counsel for Plaintiffs

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all triable issues.

/s/Carasusana B. Wall

Carasusana B. Wall (0090234)